REMARKS

Amendments to the Claims

Claims 1, 3-9 and 14 are under examination with entry of the present Amendment. These claims have been cancelled, and new claims 15-21 are presented for consideration. No new matter has been added with the amendments made herein. Support for the amended claims is found throughout the application and in the as-filed claims.

Rejections under 35 U.S.C. §103

The Office Action has maintained the rejection of claims 1, 3-9 and 14 as allegedly unpatentable over Ellis *et al.* (Gut, 1998, 43:190-195) in view of Lee (U.S. Patent No. 5,367,054) for the reasons provided on pages 3-6 of the Office Action. The Office Action alleges that given that Ellis teaches an IgG polyclonal antibody against gliadin, it would have been obvious to make an IgY polyclonal antibody against gliadin in view of the well-known IgY technology and advantages of IgY taught by Lee.

In the interest of advancing prosecution but without acquiescing to this rejection, Applicant has presented new claims 15 and 21. Claims 15 and 21 are novel in that they recite polyclonal IgY antibodies specific to one or more of gliadin, HMG and LMG. Such antibodies have not been specifically described in the prior art. The claims further provide that the antibodies bind to gliadin, HMG and/or LMG in the gastrointestinal tract of a subject, so as to prevent transport into the mucosal membrane.

It is acknowledged by Applicant that claims 15 and 21 contain functional limitations. However, it is clear that functional limitations are permitted in a claim, and may serve to distinguish the prior art. (See MPEP para. 2173.05, *In Re Swinehart* 439 F.2d 210, 169 USPQ 226 (CCPA 1971)). In this case, the functional limitations place definite boundaries on the patent protection sought by the Applicants in this case. (*In re Barr*, 444 F.2d 588, 170 USPQ 33 (CCPA 1971))

A functional limitation is particularly suitable for claims involving antibodies, as antibodies are frequently characterized and described in terms of their binding affinity for a particular antigen. A functional limitation must be evaluated and considered just like any other limitation of a claim, for what it means to a person of skill in the art.

In this case, the functional limitations in claims 15 and 21 place definite boundaries on the scope of the claim. One skilled in art would clearly understand that the claimed subject matter must be specific for the recited antigens, bind to them in the gastrointestinal tract of a subject (implying stability in such an environment), and prevent transport into the mucosal membrane. The claim boundaries are clearly established, and would be well understood by one skilled in the art.

These limitations are not taught in the prior art. The claims exclude compositions containing IgG antibodies as taught by Ellis. Further, the polyclonal IgG antibodies of Ellis *et al.* bind to gluten in diluted extracts of food samples in an *in vitro* sandwich ELISA, and the polyclonal IgY egg yolk antibodies described in Lee are not directed to any particular antigen except for bacterial species or subtypes. The proposed combination of Ellis *et al.* and Lee does not teach, suggest or disclose IgY polyclonal antibodies having the functional ability to bind to gluten components in the gastrointestinal tract and prevent transport into the mucosal membrane.

While Lee describes a process to create IgY polyclonal antibodies generally, it cannot necessarily be considered an immediate straightforward task to adapt the teaching in Lee to the presently claimed therapeutic composition comprising gluten-binding antibodies as taught by Ellis *et al.* One skilled in the art, given the teachings of the cited prior art, would understand that each antibody formulation must be created based upon, for example, desired protein concentration, stability of the protein at relevant temperatures, aggregation or fragmentation rates for each protein, and desired route of administration, to name a few parameters. Given the many parameters to consider, there is nothing routine or predictable about formulating an antibody composition for therapeutic use, as presently claimed, which comprises IgY polyclonal

antibodies having the recited function, and capability of binding to ingested gluten. Ellis *et al.* and Lee thus do not render obvious the present claims.

Claims 16-20 depend from claim 15, and are submitted to be patentable for at least the same reasons given above.

CONCLUSION

In view of the foregoing remarks and amendments, it is respectfully submitted that this application is in condition for allowance and allowance thereof is respectfully requested.

Respectfully submitted,

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